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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,140	12/30/1999	LOUISE JANE BYASS	LEVER-620X(F	5766

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UNILEVER
PATENT DEPARTMENT
45 RIVER ROAD
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EXAMINER
LIU, SAMUEL W

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/308,140	BYASS ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2003 (Paper NOs. 25 and 26)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-19,21 and 23* is/are pending in the application.

4a) Of the above claim(s) *5,6,8-10,16 and 17* is/are withdrawn from consideration.

5)☒ Claim(s) *2,3,11-14,18,19,21 and 23* is/are allowed.

6)☒ Claim(s) *1,4 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' amendment filed 25 June 2003 (Paper No.26) as to amendment of claims 2, 21 and 23, amendment filed 25 June 2003 (Paper No.25) as to cancellation of claim 22 and amendment of claims 1-2, 4, 7, 11, 18 and 23, and applicants' request filed 25 June 2003 (Paper No. 24) for exertion of time of two months have been entered. Thus, claims 1-4, 7, 11-14, 18-19, 21 and 23 are pending to which the following is or remains applicable. Please note that grounds of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

Objection to Claims

The disclosure is objected to because of the following informalities:

In claim 3, "the fragments (A-E)" should be changed to "the sequences (SEQ ID NOs: 1-5)".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of the peptide core sequences of SEQ OID NOs:1-5 for the claimed antifreeze protein (AFP) (claims 1-4, 11 and 18), a method of preparing the protein

(claim 7) thereof, a food product comprising the AFP protein (claims 12-13, 19, 21 and 23) and the process of making the food product thereof (claim 14). Applicant is not in possession of any isoforms or derivative of isolated AFP polypeptide having 36 KDa (see claim 1) and any isoforms or derivative of the full-length sequence of SEQ ID NO:7 (see claim 4).

The specification does not define the isoform or derivative of the claimed AFP polypeptide. The current claim language of claims 1 and 4 appears to encompass a large number of the polypeptide variants including genetic mutations (substitution, deletion, insertion and rearrangement), chemical modification (e.g., lipidation, phosphorylation, glycosylation and ubiquitination) and any modification of side chain or/and α-amino group or/and α-carbon of amino acid residues thereof. The specification provides insufficient teaching, guidance, and no working examples as to how to make and use the variant molecules which are structurally and functionally divergent from the core sequences of SEQ ID NOs: 1-5. Thus, applicants are not in possession of any isoforms and/or derivative of the claimed AFP polypeptide comprising the sequence in the order of SEQ ID NOs: 1, 2, 4, 3, 3 and 5.

Applicant has disclosed only the peptide sequences SEQ ID NOs:1-5 and 7; therefore, the skilled artisan cannot envision all the contemplated peptide sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993).

Making changes from the sequences (SEQ ID NOs; 1-5 or 7) does not provide maintaining the same three-dimensional structure of the polypeptide encoded by the sequences thereof. Because the specification fails to describe the consequence of the mutants or isoforms or derivatives and the common attributes or characteristics that identify any AFP variants, the specification is thus insufficient to enable skilled artisan to practice the invention as broadly claimed without an undue amount of experimentation.

Description of invention's reduction to practice, unaccompanied by any meaningful, distinguishing characteristics of evolved the polypeptide isoform or derivatives and their use as antifreeze composition is insufficient to satisfy written description requirement of 35 U.S.C. §112, since inventors could have provided description of isoforms or derivatives of SEQ ID NOs:1-5, since actual reduction to practice may demonstrate possession of embodiment of invention, but it does not necessarily describe what invention is, and since, in context of present case, disclosure of manner in which invention was reduced to practice does not satisfy more fundamental written description requirement set forth in Section 112.

The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, *i.e.*, structure or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that the applicants were in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of the polypeptide isoforms or/and derivatives to describe its use in antifreeze composition, e.g., a food product. Thus, Applicant was not in possession of the claimed polypeptide isoform or derivative. *See University of California v. Eli Lilly and co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

In consideration of the issued stated *supra*, the amount and level of experimentation needed is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites "the carrot material"; the recitation is unclear as to whether or not the claimed polypeptide is isolated from a material containing carrot, e.g., a carrot-containing food or any substance containing carrot.

Claim Rejection –Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claim 1 is rejected under the judicially created doctrine of the obviousness-type double patenting of the claim in US Pat. No. 6096867. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1 and 2 of US Pat. No. 6096867 discloses AFP polypeptide isolated from carrot (see claim 2, line 60) and teaches that the AFP polypeptide has molecular weight about 38 KDa which meets the limitation set forth in the instant claim 1 (see Example VII and column 12, lines 25-30). Thus, the disclosure of US Pat. No. 6096867 is the obvious variation of claim1 of the current invention; the claims of the present application are not patentably distinct from the claims of US Pat. No. 6096867.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Conclusion

Claims 1, 4 and 7 are rejected. Claims 2-3, 11-14, 18-19, 21 and 23 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

Samuel Wei Liu

July 29, 2003